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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,268

09/09/2004

Seppo Yla-Herttuala

GJE-7452

4903

23557 7590 05/03/2007  
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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/507,268

Applicant(s)

YLA-HERTTUALA ET AL.

Examiner

Marcia S. Noble

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-9 are pending. Claims 10-19 are canceled and claims 1 and 6 are amended by the amendment filed 2/9/2007. Claims 1-9 are under consideration.

### *Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 stand under 35 U.S.C. 112, first paragraph, as set forth on pages 2-8 in the Office Action, mailed 8/9/2006, because the specification, while being enabling for the following: a baculovirus comprising a vp39 fusion protein, wherein the C- or N-terminus of the vp39 is modified and wherein fusion protein is expressed on the surface of the baculovirus capsid, does not reasonably provide enablement for a baculovirus of which the capsid has been modified wherein any capsid protein or p 24 or p80 are modified such that said capsid displays one or more heterologous peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

Applicant traverses this rejection on the grounds that cited prior art demonstrated that modifications to capsid proteins can be done by the skilled person without difficulty

and that the newly modified capsid can be readily sequenced and therefore any desired modification can be made (par bridging p.4-5 of remarks filed 2/9/2007). They further argue that making such modifications to capsid proteins would be considered routine in the art (p. 5, line 9 of remarks filed 2/9/2007). Applicant sights Oker-Blon et al to support that other capsid proteins can be modified stating that molecular biology has allowed for "different strategies for presentation of foreign peptide and proteins on the surface of budding virons...." (p. 5). Applicant acknowledges that it is conceivable that certain constructs may not result in the desired modified baculovirus, however, mere inoperable embodiments do not rendered a claim not enabled (p. 6).

Applicant's arguments have been fully considered and have not been found persuasive.

As previously stated in the Office action, mailed 8/9/2006 (p. 6), "Oke-Blom et al (Briefing in Functional Genomics and Proteomis 2(3):244-253, 2003) suggest that the three dimensional structure of baculovirus *AcMNPV* has not been determined and therefore the structural interactions and functional elements of capsid proteins have not been fully described, developed, and understood (p. 249, col 1 par 1). Since the structure/function of the capsid proteins of baculovirus have not been well described in the art, an artisan would need to look to over examples in the art to determine functional/structural limitations of capsid proteins." The Office action further demonstrated with the art that some modifications will not be functional as taught by Thomsen et al (1995; of record) and West et al. (2006; of record) (see page 4 of the Office Action, mailed 8/9/2006. Therefore, because it is not established in the art which

components can and can not be modified because the art has not determined all of the structural and functions interactions of capsid proteins, an artisan would need specific guidance from the specification as to the exact nature of where and how the capsid protein has been modified. The specification only provides this type of specific guidance for vp39 and therefore the invention is only enabled for vp39.

Therefore, contrary to Applicant's assertion, one of skill in the art would need more specific guidance as to what specific sequences would need to be provided for an artisan to make other modifications to the capsid because elements of baculovirus and capsid structure and function are not known as taught by Oke-Blom et al, Thomsen et al, and West et. It is acknowledged that the methods by which modification can be made to a capsid protein are established in the art, however, this does not mean that making any modification because the method is known results in a functional baculovirus. It is also acknowledged that inoperable embodiments do not render an invention lacking enablement. However, the specification and art must provide adequate disclosure of the underlying structural and functional relationships that are common to the different species of invention that would reasonably allow for most of the embodiments to be functional. In the instant case, too little is understood about the underlying structural/functional interaction in the formation of a baculovirus to assume the teaching of one species of modification to vp39 could predictably be applied to other capsid proteins to result in a functional baculovirus, and therefore, the enablement issue exceed mere inoperable embodiments.

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Therefore, because the art and specification do not provide adequate guidance to teach a modification to any capsid protein that results in a functional baculovirus, the invention is not enabled for the full breadth of the claims. Therefore, the instant rejection is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 1-7 under 35 U.S.C. 102(b) as being anticipated by Liu et al (Acta Virologica, 2000, 44: 157-161) as set forth on pages 8-10 in the Office Action, mailed 8/9/2006, is withdrawn.

Applicant traverses this rejection on the grounds that the amendment to the claims to recite "said capsid displays one or more peptides that are heterologous to the baculovirus" obviates the instant rejection because Liu et al does not teach this embodiment (p. 6, last par).

Applicant's argues have been fully considered and are persuasive. Therefore, the rejection is withdrawn.

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4. Claims 10 and 12, rejected under 35 U.S.C. 102(b) as being anticipated by Van Loo et al (Journal of Virology, 2001, 75(2): 961-970; IDS), have been canceled.

Therefore, the rejection is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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